

Notice of Allowability

Application No.

09/497,422

Examiner

Blessing M. Fubara

Applicant(s)

BERRY ET AL.

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment/remarks filed 08/04/06.
2. ☒ The allowed claim(s) is/are 10, 11, 15-18, 21-23, 27 and 29-32 (claims are renumbered).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

The drawings filed 2/03/2000 have been accepted

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 8/04/2006
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 10/31/06
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Edgar R. Cataxions on 10/31/06.

The application has been amended as follows:

In the claims:

Claim 10 (Currently Amended)

A stable non-aqueous single-phase biocompatible viscous vehicle, comprising:

a polymer consisting of polyvinylpyrrolidone;

a surfactant consisting of glycerol monolaurate; and

a solvent consisting of lauryl lactate;

wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise[, and the vehicle is adapted for use as an injectable vehicle or for use in an implantable delivery device].

Claim 11 (Currently Amended)

A stable non-aqueous single-phase biocompatible viscous vehicle, comprising:

a polymer consisting of polyvinylpyrrolidone;

a surfactant consisting of polysorbate; and

a solvent consisting of lauryl lactate;

Art Unit: 1618

wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise[, and the vehicle is adapted for use as an injectable vehicle or for use in an implantable delivery device].

Claim 15 (Currently Amended)

A non-aqueous formulation comprising at least one beneficial agent uniformly suspended in a non-aqueous single-phase biocompatible viscous vehicle, the non-aqueous single-phase biocompatible viscous vehicle comprising:

- a polymer consisting of polyvinylpyrrolidone;
- a surfactant consisting of glycerol monolaurate or polysorbate; and
- a solvent consisting of lauryl lactate[; wherein, the vehicle is adapted for use as an injectable vehicle or for use in an implantable delivery device].

Claims 35-38 (Canceled)

Claims 46-51 (Canceled)

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance: Gyory (5,668,170) provided by applicant on Form 1449 filed 8/4/06, studies electrotransport effect of surfactants such as lauryl sulfate (column 12, line 64), polyethylene glycol monolaurate (column 12, lines 65 and 66), lauryl lactate (column 13, line 2), polysorbate Column 13, line 4), dodecyl pyrrolidone (column 13, line 6) and decyl methyl sulfoxide (column 13, line 8). To study the electrotansport enhancing effects of the above surfactants, each surfactant was added to metoclopramide hydrochloride (Example 1) in aqueous solution. Polyvinyl pyrrolidone may be blended with the drug (column 10, lines 32, 33, 39 and 40) in the drug/agent reservoir. Table 1 looks at the effect

Art Unit: 1618

of the individual surfactant on the flux of the metoclopramide. Gyory at column 14, line 54 through column 15, line 16 discusses that lauryl lactate, while reducing skin resistivity, does not enhance mass flux of metoclopramide (column 14, lines 63-65); that polysorbate-20 failed to have significant effect on either the electrotransport flux of metoclopramide or skin resistivity (column 14, line 66 through column 14 line 1). Thus, while it is clear that Gyory's composition is aqueous and differs from the non-aqueous single phase viscous composition of the instant claims, Gyory's findings does not encourage the use of either lauryl lactate or polysorbate as mass flux enhancers for the beneficial agent, metoclopramide. Gyory does not also show that a combination of surfactants such as lauryl lactate and polysorbate would enhance the mass flux of metoclopramide so that there would not be motivation to use a combination of lauryl lactate and polysorbate with metoclopramide to enhance the mass flux.

3. An obviousness type double patenting rejection would be made in the later filed co-pending application number 10/319,277 (filed 12/12/2002), while this application, which is an earlier filed application (filed 2/3/2000) is allowed to go to issue.

4. Therefore, the pending claims are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1618

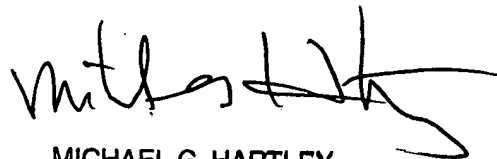
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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